UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHANNON MAHONEY, individually and on behalf of herself and all others similarly situated,

Plaintiff,

v.

ENDO HEALTH SOLUTIONS, INC., a Delaware corporation; ENDO PHARMACEUTICALS, INC., a Delaware corporation; GENERICS INTERNATIONAL (US PARENT), INC., a Delaware corporation d/b/a Qualitest Pharmaceuticals; GENERICS INTERNATIONAL (US), INC., a Delaware corporation; GENERICS BIDCO I, LLC, a Delaware limited liability company; GENERICS BIDCO II, LLC, a Delaware limited liability company; GENERICS INTERNATIONAL (US HOLDCO), INC., a Delaware corporation; GENERICS INTERNATIONAL (US MIDCO), INC., a Delaware corporation; and VINTAGE PHARMACEUTICALS, LLC, a Delaware limited liability company,

Defendants.
_____/

CASE NO. 15 Civ. 9841

CLASS ACTION

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Shannon Mahoney ("Plaintiff" or "Mahoney"), on behalf of herself and all others similarly situated, files this Complaint against Defendants Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Generics International (US Parent), Inc.; Generics International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Holdco), Inc.; Generics International (US Midco), Inc.; and Vintage Pharmaceuticals, LLC (collectively "Defendants"), and alleges as follows:

INTRODUCTION

1. This is a class action lawsuit filed on behalf of purchasers of Qualitest Multi-Vitamin with Fluoride Chewable Tablets ("Chewable Tablets"), which are available only by prescription. Unlike children's multivitamins available over the counter throughout the United States, Qualitest-branded Chewable Tablets are marketed and sold for a specific purpose – delivery of a fixed dose of fluoride for those children whose dentists or physicians have determined that supplemental fluoride is necessary for cavity prevention.

2. Defendants marketed and sold the Chewable Tablets purporting to contain fluoride in three different concentrations – 1 milligram, .5 milligrams, and .25 milligrams of fluoride per tablet. The concentration is specified by the prescribing practitioner in a prescription, and the specific concentration dispensed is clearly disclosed on the product label.

3. From some point in 2007 through July 2013, however, the Qualitest Chewable Tablets Defendants manufactured consistently contained less than 50% of the amount of fluoride claimed on their labels. Defendants misrepresented the true dosage of the Qualitest products for years and deceived millions of parents, dentists, and pediatricians as to the amount of fluoride being delivered to children.

4. Based on the current state of scientific research, delivery of a sub-therapeutic dose of fluoride has the same effect as a placebo.

PARTIES, JURISDICTION, AND VENUE

5. Plaintiff is, and at all material times was, a resident and citizen of Orange County, New York. Plaintiff purchased Qualitest-branded Chewable Tablets during the class period from pharmacies in New York for her minor children, B.M. and R.M.

6. Defendant **Endo Health Solutions, Inc.**, ("Endo Health") formerly known as Endo Pharmaceuticals Holdings, Inc., is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health describes itself as a "specialty healthcare solutions company focused on branded and generic pharmaceuticals, devices and services." The Qualitest brand is one of Endo Health's four business "segments."

7. Defendant **Endo Pharmaceuticals, Inc.** ("Endo") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo purchased the Qualitest brand from a subsidiary of Apax Partners, L.P., in 2010.

8. Defendant **Generics International (US Parent), Inc.** ("GIUSP") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. GIUSP is a direct subsidiary of Endo. According to Endo Health filings with the Securities and Exchange Commission, GIUSP does business as "Qualitest Pharmaceuticals." Endo purchased GIUSP from a subsidiary of Apax Partners, L.P., in 2010.

9. Defendant **Generics International (US), Inc.** ("GIUS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. According to the Alabama Secretary of State, GIUS had its principal office at 130 Vintage Drive in Huntsville, Alabama, until February 2013. GIUS is indirectly owned by GIUSP.

10. Defendants **Generics Bidco I, LLC** and **Generics Bidco II, LLC** (together, "Generics Bidco") are Delaware limited liability companies that, upon information and belief, have their principal place of business in Malvern, Pennsylvania. Plaintiff believes that Generics Bidco may have been involved in the manufacturing or distribution of the generic drugs labeled with the Qualitest brand.

11. Defendants **Generics International (US Holdco), Inc.** ("Generics Holdco") and **Generics International (US Midco), Inc.** ("Generics Midco") are Delaware corporations that, upon information and belief, have their principal places of business in Malvern, Pennsylvania. Plaintiff believes that Generics Holdco and Generics Midco may have been involved in the manufacturing or distribution of the generic drugs labeled with the Qualitest brand.

12. Defendant **Vintage Pharmaceuticals, LLC** ("VPLLC") is a Delaware limited liability company with its principal place of business at 130 Vintage Drive in Huntsville, Alabama. Upon information and belief, VPLLC currently manufactures all generic drugs labeled with the Qualitest brand, including the Chewable Tablets that give rise to the claims in this Complaint.

13. This Court has jurisdiction under 28 U.S.C. § 1332(d)(2)(A) because this is an action for a sum exceeding $5,000,000, exclusive of interest and costs, and Plaintiff is a citizen of New York, and at least one Defendant is a citizen of a state other than New York.

14. This Court has personal jurisdiction over each of the Defendants. Defendants contracted to supply the defective Chewable Tablets to consumers in New York. As such, Defendants have purposely availed themselves of the privilege of conducting business in New York and are subject to the jurisdiction of New York courts. N.Y. C.P.L.R. § 302(a)(1). Moreover, certain Defendants, including Endo and GIUS, who have authority to act on behalf of the remaining Defendants, are registered to do business in New York, which is a constructive consent to personal jurisdiction.

15. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), because Plaintiff's causes of action accrued within this judicial district and a substantial part of the events and omissions giving rise to the Plaintiff's claims occurred here. Plaintiff is a resident of

Montgomery, Orange County, New York, and purchased the defective Chewable Tablets at a pharmacy in this District.

FACTUAL ALLEGATIONS

ADA Recommendations on Fluoride

16. It is now universally accepted that fluoride helps prevent "dental caries," more commonly known as tooth decay. Dental caries is an infectious, transmissible disease in which bacterial by-products (i.e., acids) dissolve the mineralized surfaces of teeth. Unchecked, the bacteria can penetrate the dissolved tooth surface, attack the underlying dentin, and reach pulpal tissues. Dental caries can result in loss of tooth structure, pain, and tooth loss and can progress to acute systemic infection. The Centers for Disease Control and Prevention (the "CDC") reported that from 1999 through 2004, 42% of U.S. children ages 2 to 11 years experienced dental caries in their primary teeth and 59% of U.S. adolescents ages 12 to 19 years experienced dental caries in their permanent teeth.

17. The American Dental Association ("ADA") and the American Academy of Pediatrics ("AAP") both advocate that all cities, towns and other municipalities "fluoridate" their community drinking water. This process involves adding fluoride to drinking water, thus assuring that people, particularly children, receive daily fluoride dosages in the their diet. According to the CDC, in 2010, 69% of the United States population received optimally fluoridated community drinking water while 31%, or approximately 95,480,000 people, did not receive fluoride through community water sources.

18. For communities that do not have fluoridated water, the ADA and the AAP recommend those children up to age 16 receive daily dietary fluoride supplements in order to

prevent cavities and tooth decay. These dietary fluoride supplements can take the form of topical applications, liquid drops, chewable fluoride tablets, or chewable multivitamins with fluoride.

19. Since 1958, the ADA and the AAP have been publishing recommended dietary fluoride supplemental dosage schedules for children. The following recommendations were adopted in 1994 and restated in 2010. The recommendation includes a sliding scale to account for a child's age and the amount of fluoride in the drinking water of the community where the child lives:

Dietary fluoride supplement schedule

Age	Fluoride ion level in drinking water (ppm)*		
	Less than 0.3ppm	0.3-0.6ppm	Greater than 0.6 ppm
Birth-6 months	None	None	None
6 months-3 years	0.25 mg/day**	None	None
3-6 years	0.50 mg/day	0.25 mg/day	None
6-16 years	1.0 mg/day	0.50 mg/day	None

*0.1 part per million (ppm) = 1 milligram/liter (mg/L)
**2.2 mg sodium fluoride contains 1 mg fluoride ion

These recommendations are hereinafter referred to as the "ADA-AAP Guidelines." Dentists and physicians throughout the United States rely upon this chart in prescribing fluoride supplements to children.

The Distinction Between "Fluoride" and "Sodium Fluoride"

20. The information marked with a double asterisk "**" in the ADA-AAP Guidelines chart clarifies the nature of the fluoride recommendation. Dental fluoride can be obtained from different sources, most commonly "sodium fluoride" and "stannous fluoride." Sodium fluoride is a specific salt form of fluoride. "Sodium fluoride" is not the same as "fluoride." Sodium Fluoride (NaF) disassociates into 54.5% sodium (Na^+) and 45.5% fluoride ion (F^-). The fluoride ion accounts for 45.5% of the sodium fluoride by weight.

21. As noted in the ADA chart, it takes 2.2 milligrams of sodium fluoride to yield 1 milligram of fluoride. Thus, the official ADA and AAP recommendation – and the one relied upon by dentists and pediatricians – calls for prescribing dosages of fluoride ion, not dosages of sodium fluoride.

The Market for Chewable Fluoride Vitamins

22. To satisfy the ADA-AAP Guidelines, many companies manufacture and sell products marketed as chewable "Multivitamins with Fluoride." As of 2013, at least fifteen (15) companies were in the business of selling chewable "Multivitamins with Fluoride" in the United States. Universally, these companies manufacture and sell their "Multivitamins with Fluoride" products in only three fluoride dosage sizes – 0.25 mg, 0.5 mg and 1 mg of fluoride. These dosage amounts correspond to the ADA-AAP Guidelines' dosage recommendations. Thus, a child 3-6 years old, who lives in a community with less than 0.3 parts per million of fluoride in community drinking water (or obtained through other daily sources), should be prescribed a daily 0.5 mg fluoride supplement tablet. A child 6-16 years old, who lives in same community, should be prescribed a daily 1.0 mg fluoride supplement tablet. And so on.

23. These fluoride products are not sold "over the counter." They must be prescribed by a licensed dentist or physician in order to be purchased. At the same time, however, these products are not approved by the FDA. Sodium fluoride chewable tablets are registered in the FDA National Drug Code Registry as "unapproved drug other." Accordingly, neither the product nor the labeling needs to be approved by the FDA.

Defendants' Labeling Claims

24. Defendants, through one or more of their subsidiaries, were for many years the dominant manufacturer and distributor of "Multivitamins with Fluoride" in the United States,

accounting in some years for about one-half of all such products sold. Defendants manufactured and distributed Chewable Tablets under the "Qualitest Pharmaceuticals" brand in all three dosage sizes – 0.25 mg, 0.5 mg., and 1 mg – and in numerous flavors, grape, cherry, etc. Among others, Defendants used the following National Drug Codes: 00603-4381-21, 00603-4382-21, 00603-4383-21, 00603-4713-21, 00603-4714-21, and 00603-4715-21.

25. Upon information and belief, Defendants also produced Qualitest-branded Chewable Tablets for repackaging and relabeling by other companies, including Physicians Total Care, Inc. ("PTC").

26. Defendants' labeling for these products consisted of two parts, an outside label affixed to the bottle and a package insert. Plaintiff has attached as **Composite Exhibit A** sample outside labels for each dosage size of Qualitest-branded Chewable Tablets. Plaintiff has attached as **Exhibit B** a sample package insert, the relevant language of which is the same for every package of Qualitest-branded Chewable Tablets, regardless of dosage size. **Exhibit C** is a sample outside label for PTC-branded Chewable Tablets, which makes substantially the same representations as found on the Qualitest-branded Chewable Tablet labels.

27. In bold letters, the outside of each label states the alleged dosage of fluoride. As an example, the outside labels attached as Exhibit A and Exhibit C identify the title of the product as follows:

"MULTI-VITAMIN WITH FLUORIDE CHEWABLE TABLETS GRAPE 1 mg."

See Exhibits A & C. The "Nutrition Facts" component of the outside label repeats these claims:

"FLUORIDE . . . . . 1 mg"

Id.

28. The outside labels for both Qualitest-branded and PTC-branded Chewable Tablets state unequivocally, in two places, that the tablets contain 1 milligram of "fluoride." The pattern repeats itself for each dosage size as well. *See Id.*

29. The package inserts for Qualitest-branded Chewable Tablets repeat the fluoride claim in a section titled "INDICATIONS AND USAGE." That section follows the ADA and AAP guidelines precisely in terms of the dosage schedule for fluoride. It provides:

> Supplementation of the diet with fluoride for caries prophylaxis.
>
> Multivitamin with 1 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 6-16 years of age in areas where the water fluoride level is less than 0.3 ppm.
>
> Multivitamin with 0.5 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the water fluoride level is less than 0.3 ppm, and for children 6 years of age and above where the drinking water contains 0.3 through 0.6 ppm of fluoride.
>
> Multivitamin with 0.25 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the drinking water contains 0.3 through 0.6 ppm of fluoride.
>
> Multivitamin with Fluoride Chewable Tablets supply significant amounts of Vitamins A, C, D, E thiamin, riboflavin, niacin, vitamin B6, vitamin B12, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop.
>
> Thus, in a single easy-to-use preparation, children obtain ten essential vitamins and the important mineral, fluoride.
>
> The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

See Exhibit B. Upon information and belief, PTC-branded tablets contained package inserts with nearly identical information. Based on this insert, Defendants knew and expected that dentists and physicians would prescribe and dispense Chewable Tablets to children to prevent tooth decay, i.e., for caries prophylaxis.

30. As indicated above, the package insert even cites to the ADA-AAP Guidelines and recommends that, for example, the "1 mg" tablet be prescribed to children between 6 and 16 years old who live in areas with less than 0.3 ppm fluoride in the drinking water. This leaves no doubt that the Qualitest-branded Chewable Tablet purported to deliver 1 milligram of fluoride. In reality, as set forth below, the Qualitest-branded Chewable Tablets delivered, on average, less than half that amount. Upon information and belief, the PTC-branded tablets will reveal the same result.

Qualitest Products Do Not Contain the Claimed Amount of Fluoride

31. From a period of time beginning in 2007 through July 2013, Defendants, operating under the "Qualitest Pharmaceuticals" or "Vintage Pharmaceuticals" brands, manufactured Chewable Tablets that delivered, on average, less than one half of the amount of fluoride claimed on the label.

32. These Chewable Tablets were manufactured in "batches" of up to three million tablets at a facility in Huntsville, Alabama. To manufacture each batch, Defendants created a "manufacturing batch record" that contained a "master formula" specifying the amount of each ingredient used. During the relevant period, Defendants relied on the same three master formulas to manufacture the 1 mg, 0.5 mg, and 0.25 mg Chewable Tablets.

33. Those master formulas used 2% sodium fluoride as the source of fluoride ion. Instead of using 2.2 mg of sodium fluoride as an ingredient to secure 1 mg of fluoride ion for the 1 mg Chewable Tablet, however, Defendants used only 1 mg of sodium fluoride. Similarly, instead of using 1.1 mg of sodium fluoride for the 0.5 mg tablet and 0.55 mg of sodium fluoride for the 0.25 mg tablet, Defendants used 0.5 mg of sodium fluoride and 0.25 of sodium fluoride, respectively.

34. In other words, a "1 mg" Qualitest-branded Chewable Tablet did not contain 1 milligram of fluoride as claimed. It contained approximately 45% of the alleged dosage of fluoride. The same is true of the lower dosage tablets: the 0.5 mg and 0.25 mg Chewable Tablets both contained, on average, approximately 45% of the claimed dosage of fluoride.

35. As a result of Defendants purposeful or reckless conduct, the Qualitest Chewable Tablets did not contain 1.0 mg, 0.5 mg, and 0.25 mg of fluoride ion, respectively. The 1.0 mg Qualitest Chewable Tablet contained approximately 0.44 mg of fluoride ion; the 0.5 mg Qualitest Chewable Tablet contained approximately 0.22 mg of fluoride ion; and the 0.25 mg Qualitest Fluoride Tablet contained approximately 0.11 mg of fluoride ion.

36. This subpotency issue was not isolated to particular bottles, lot numbers, NDC numbers, flavors, dosages, or shipments. Instead, the defect pervaded *all* Chewable Tablets "batches" manufactured by Defendants from 2007, until the defect was discovered by Defendants in mid-2013.

37. Given Defendants' market share in this category, Defendants' subpotent Chewable Tablets led to widespread under-delivery of fluoride from 2007 through late 2013. That is, dentists and physicians believed that the Qualitest Chewable Tablets (both Qualitest-branded and PTC-branded) contained the amount of fluoride ion claimed on the label but, in reality, they did not.

38. Defendants cannot argue that the dosage of "fluoride" on the label means "sodium fluoride." Given the ADA-AAP Guidelines, recommending 1.0 mg, 0.5 mg, or 0.25 mg of fluoride ion, respectively, no rational dentist or doctor would prescribe a 1.0 mg tablet of "sodium fluoride." In that event, a child prescribed the 1.0 mg Qualitest Chewable Tablet would be required to consume 2.2 tablets to meet the ADA-AAP Guidelines. The

"INDICATIONS AND USAGE" set forth in Exhibit B make clear that Defendants did not intend for children to take 2.2 tablets to reach the correct dosage of fluoride ion.

39. As a result, children who were prescribed Qualitest Chewable Tablets in accordance with the recommendations of the ADA-AAP Guidelines discussed above (taking into account the pertinent variables including fluoridation of drinking water and age) and consumed one Qualitest Chewable Tablet per day, as the product labeling instructed, received in any given tablet approximately 44% of the fluoride ion recommended by the ADA-AAP. These children were, as a result, exposed to an increased risk for developing tooth cavities.

CLASS ACTION ALLEGATIONS

40. Plaintiff brings this Complaint as a class action pursuant to Federal Rule of Civil Procedure 23.

Class Definitions

41. Plaintiff seeks to represent the following Classes:

> All persons and entities who, during the applicable limitations period, purchased Chewable Tablets manufactured between January 1, 2007 and July 31, 2013, branded "Qualitest Pharmaceuticals," "Vintage Pharmaceuticals," or "Physicians Total Care," purportedly containing doses of fluoride of 1.0 mg, 0.5 mg, or 0.25 mg ("the Class"). Excluded from the Class are Defendants and their officers, directors, agents, and employees, and all governmental entities.

and

> All New York persons and entities who, during the applicable limitations period, purchased Chewable Tablets manufactured between January 1, 2007, and July 31, 2013, branded "Qualitest Pharmaceuticals," "Vintage Pharmaceuticals," or "Physicians Total Care," purportedly containing doses of fluoride of 1.0 mg, 0.5 mg, or 0.25 mg ("New York Subclass"). Excluded from the Class are Defendants and their officers, directors, agents, and employees, and all state and federal governmental entities.

42. The members of the Classes number in the thousands and joinder of all Class Members in a single action is impracticable.

43. This class action is brought pursuant to Rule 23(b)(3) because the questions of law or fact common to Plaintiff's claims and the Class Members' claims predominate over any question of law or fact affecting only individual Class Members.

44. Defendants have subjected Plaintiff and the members of the Class to the same unfair, unlawful, and deceptive practices and harmed them in the same manner.

Numerosity

45. The individual Class Members are so numerous that joinder of all members in a single action is impracticable. Upon information and belief, there are thousands of members of the Class. For instance, Plaintiff estimates that upwards of 40 million defective Chewable Tablets may have been sold in the twelve-month period running from February 2012 to February 2013, all of which suffered from the same defect. The Class includes all purchasers of Chewable Tablets over a six-year period.

46. Individual Class Members may be identified by reference to objective criteria contained within the Class Definition. Indeed, because the proposed Class is comprised solely of individuals who obtained written physicians' prescriptions for Chewable Vitamins, and those prescriptions were filled at licensed pharmacies, objective and reliable third-party records exist for the identification of all Class Members. For instance, New York law requires that "[r]ecords of all prescriptions filled or refilled shall be maintained for a period of at least five years," and the "records shall indicate [the] date of filling or refilling" as well as the "patient's name and address." N.Y. Educ. Law § 6810(5).

47. In the alternative, based on the relatively low dollar value of individual claims and the correspondingly low risk of fraud or misrepresentation, individual Class Members may self-

identify through sworn affidavits or certifications in the post-judgment claims administration process.

Commonality/Predominance

48. Common questions of law and fact exist as to Plaintiff's and the Class Members' claims. These common questions predominate over any questions solely affecting individual Class Members, including but not limited to, the following:

a. Whether Defendants' Chewable Multivitamins with Fluoride contained the concentration of fluoride represented on its label and packaging during the Class period;

b. Whether the fact that Defendants' Chewable Multivitamins with Fluoride did not contain the labeled concentration of fluoride during the Class period rendered the vitamins valueless; and

c. Whether Defendants were unjustly enriched by virtue of the sale of Chewable Multivitamins with Fluoride that did not contain the labeled concentration of fluoride during the Class period.

49. Plaintiff's claims are typical of the Class Members' claims because of the uniformity of Defendants' unlawful conduct. Plaintiff, like all Class Members, was damaged through their payment of money for Chewable Tablets that Defendants falsely claimed to contain certain concentrations of fluoride ion. Instead, Defendants' Chewable Tablets contained only a sub-therapeutic dose of fluoride ion, rendering them clinically and economically valueless.

50. Each Class Member has sustained damages in the same manner as Plaintiff, as a result of Defendants' wrongful conduct.

Adequacy

51. The Plaintiff will fairly and adequately protect and represent the interest of each member of the Class, because she has suffered the same wrongs as the Class Members.

52. Plaintiff is fully cognizant of her responsibilities as Class Representative and has retained the law firm of McCabe Rabin, P.A. to prosecute this case. The law firm is experienced in complex class action litigation, including litigation related to unfair and deceptive trade practices, and has the financial and legal resources to meet the costs of, and understand the legal issues associated with, this type of litigation.

53. Class action treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein, because such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of evidence, effort and expense that numerous individual actions would engender. Moreover, Plaintiff expects that each individual claim for damages will be relatively small, making them extremely inefficient to prosecute individually.

The Prerequisites of Rule 23(b)(3) Are Satisfied

54. The questions of law and fact enumerated above predominate over questions affecting only individual members of the Class, and a class action is the superior method for fair and efficient adjudication of the controversy.

55. The likelihood that individual members of the Class will prosecute separate actions, and their interest in so doing, is small due to the extensive time and considerable expense necessary to conduct such litigation, and the relatively small claims for damages that each of them is likely to have individually.

56. This action will be prosecuted in a fashion to ensure the Court's able management of this case as a class action on behalf of the Class. Plaintiff knows of no difficulty likely to be encountered in the management of this action that would preclude its maintenance as a class action.

COUNT I
Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

57. Plaintiff re-alleges paragraphs 1 through 56 as if fully set forth herein.

58. The Chewable Tablets, marketed under the names of Qualitest Pharmaceuticals, Vintage Pharmaceuticals, and Physicians Total Care are consumer products as defined in 15 U.S.C. § 2301(1).

59. Plaintiff and other Class Members are consumers as defined in 15 U.S.C. § 2301(3).

60. Defendants are suppliers and warrantors as defined in 15 U.S.C. § 2301(4) and (5).

61. Plaintiff and all Class Members purchased Chewable Tablets during the class period.

62. In connection with the sale of the Chewable Tablets during the Class period, Defendants issued written warranties as defined in 15 U.S.C. § 2301(6), by representing that the Chewable Tablets contained specified amounts of fluoride, including 1 mg, 0.5 mg and 0.25 mg.

63. In fact, the Chewable Tablets did not conform to the above-referenced representations. During the Class period, Defendants manufactured the Chewable Tablets using sodium fluoride as its source of fluoride ion. Sodium fluoride contains roughly 45% fluoride ion.

64. Instead of using 2.2 mg of sodium fluoride as an ingredient to manufacture the 1.0 mg Chewable Tablet, Defendants used only 1.0 mg of sodium fluoride. As such, the 1.0 mg Chewable Tablet contained approximately 0.44 mg of fluoride ion.

65. Instead of using 1.1 mg of sodium fluoride as an ingredient to manufacture the 0.5 mg Chewable Tablet, Defendant used only 0.5 mg sodium fluoride. As such, the 0.5 mg Chewable Tablet contained approximately 0.22 mg of fluoride ion.

66. Instead of using 0.55 mg of sodium fluoride as an ingredient to manufacture the 0.25 mg Chewable Tablet, Defendant used only 0.25 mg sodium fluoride. As such, the 0.25 mg Chewable Tablet contained approximately 0.11 mg of fluoride ion.

67. By breaching its express warranty as to the fluoride ion content of its vitamins, Defendants violated the statutory rights due to Plaintiff and Class Members pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301 *et seq.*, thereby damaging Plaintiff and Class members.

68. As a result, Plaintiff and Class Members received Chewable Tablets containing approximately 45% of the recommended daily intake of fluoride ion.

69. Plaintiff and Class Members were injured as a direct and proximate result of Defendants' breach. Plaintiff and the other Class Members would not have purchased the Chewable Tablets manufactured by Defendants, had Defendants disclosed the Chewable Tablets' actual fluoride ion content.

70. Plaintiff and the Class preliminarily raise this claim for the purposes of establishing their representational capacity, pursuant to 15 U.S.C. § 2310(a)(3), (e).

COUNT II
Breach of Express Warranty

71. Plaintiff re-alleges paragraphs 1 through 56 as if fully set forth herein.

72. In connection with the sale of the Chewable Tablets, Defendants issued written warranties by representing that: (a) the 1.0 mg Chewable Tablets contained 1.0 mg of fluoride ion; (b) the 0.5 mg Chewable Tablets contained 0.5 mg of fluoride ion; and (c) the 0.25 mg Chewable Tablets contained 0.25 mg of fluoride ion.

73. In fact, the Chewable Tablets in each strength did not conform to the above-referenced representations. Because Defendants used sodium fluoride as the source of fluoride ion for the Chewable Tablets, and because Defendants did not increase the concentration of sodium fluoride to take account of the fact that it contains only 45% fluoride ion, the Chewable Tablets did not, in fact, contain the amount of fluoride ion listed on the bottle.

74. These statements were material to a reasonable consumer for children's chewable fluoride tablets. No reasonable consumer would have purchased the Chewable Tablets, if the warranties had been known to be false.

75. Plaintiff and Class Members were injured as a direct and proximate result of Defendants' breach, because they would not have purchased the Chewable Tablets if Defendant had disclosed the Chewable Tablets' actual fluoride content.

COUNT III
Negligent Misrepresentation

76. Plaintiff re-alleges paragraphs 1 through 56 as if fully set forth herein.

77. Defendants represented that the three strengths of its Chewable Tablets contained 1.0 mg, 0.5 mg, and 0.25 mg of fluoride ion, respectively.

78. Defendants misrepresented the fluoride ion content of its Chewable Tablets. During the Class period, Defendants manufactured the Chewable Tablets using sodium fluoride as its source of fluoride ion. Sodium fluoride contains roughly 45% fluoride ion, but Defendants

did not use 2.2 mg, 1.1 mg, and 0.55 mg of sodium fluoride, respectively, to reach the appropriate concentration of fluoride ion in the Chewable Tablets.

79. Defendants had a duty to disclose the correct actual amount of fluoride ion in the Chewable Tablets. Defendants assumed the duty to disclose the fluoride content of the Chewable Tablets by labeling each package with a "dosage" in line with the ADA-AAP Guidelines. By misrepresenting the actual fluoride content, Defendants breached their duty of care to Plaintiff and Class Members.

80. At the time Defendants made their misrepresentations about the amount of fluoride ion in the Chewable Tablets, Defendants either knew or should have known that the representations were false.

81. Defendants intended to induce, and actually did induce, Plaintiff and Class members to purchase the Chewable Tablets based on Defendants' representations of the fluoride ion content.

82. Plaintiff and Class Members reasonably and justifiably relied on Defendants' representations of the fluoride ion content of the Chewable Tablets.

83. Plaintiff and Class Members would not have purchased the Chewable Tablets if Defendants had correctly represented the actual fluoride ion content. No reasonable consumer would have purchased a subtherapeutic (and likely worthless) dose of medication.

COUNT IV
Unjust Enrichment

84. Plaintiff re-alleges paragraphs 1 through 56 as if fully set forth herein.

85. Plaintiff and Class members conferred benefits on Defendants by purchasing the Chewable Tablets manufactured by Defendants.

86. Defendants knowingly and voluntarily accepted and retained the financial benefit conferred by Plaintiff and Class Members.

87. Defendants have been unjustly enriched by retaining the revenues derived from Plaintiff's and Class Members' purchases of the Chewable Tablets. Retention of those revenues is unjust because Defendants misrepresented that the 1.0 mg Chewable Tablet contained 1.0 mg of fluoride ion, when in fact the 1.0 mg Chewable Tablet contained 0.44 mg of fluoride ion. Likewise, the 0.5 mg Chewable Tablet actually contained only 0.22 mg of fluoride ion, and the 0.25 mg Chewable Tablet contained only 0.11 mg of fluoride ion. As a result of the lower concentrations of fluoride ion, the Chewable Tablets were effectively worthless to Plaintiff and Class Members.

88. Defendants will be unjustly enriched if permitted to retain the aforementioned benefits, and Plaintiff and Class Members are entitled to recover the amount by which Defendants were unjustly enriched at their expense.

COUNT V
New York General Business Law § 349

89. Plaintiff re-alleges paragraphs 1 through 56 as if fully set forth herein.

90. New York General Business Law § 349, prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service[.]"

91. Defendants violated the New York General Business Law by misrepresenting the fluoride content of their Chewable Tablets. Instead of using 2.2 mg of sodium fluoride as an ingredient to manufacture the 1.0 mg Chewable Tablet, Defendants used only 1 mg of sodium fluoride, leading to a tablet containing only 0.44 mg of fluoride ion. Similarly, instead of using 1.1 mg of sodium fluoride for the 0.5 mg tablet and 0.55 mg of sodium fluoride for the 0.25 mg

tablet, Defendants used 0.5 mg and 0.25 mg of sodium fluoride, respectively, leading to tablets with only 0.22 mg and 0.11 mg of fluoride ion, respectively.

92. Defendants' misrepresentation of the fluoride content of the Chewable Multivitamins with Fluoride was likely to deceive a reasonable consumer. Defendants' representations that their Chewable Tablets contained specific concentrations of fluoride, in line with the ADA-AAP Guidelines, induced an objectively reasonable expectation that the tablets contained those recommended concentrations of fluoride ion.

93. Defendants' misrepresentation was material.

94. As a direct and proximate result of Defendants' New York General Business Law violations, Plaintiff and the New York Subclass Members suffered actual damages.

PRAYER FOR RELIEF

Plaintiff, on behalf of herself and the Class, request the following relief:

a. Certification of the Class;

b. A jury trial and judgment against Defendants Endo Pharmaceuticals, Inc.; Endo Health Solutions, Inc.; Vintage Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc.; Generics International (US Holdco), Inc.; and Generics International (US Midco), Inc.;

c. The cost of suit, including reasonable attorneys' fees;

d. General, actual, and compensatory damages in an amount to be determined;

e. Pre-judgment and post-judgment interest at the maximum rate permitted by applicable law; and

f. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury for all claims so triable, pursuant to Fed.R.Civ.P. 38(b).

Dated: December 17, 2015

Respectfully submitted,

/s Robert C. Glass
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